SEP 14 2012

510(k) Summary for the Quantel Medical SUPRA SCAN™ Delivery System

K120825

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

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Summary Preparation Date: March 27, 2012

2. Names

Device Name: SUPRA SCAN™ Delivery System

Classification Name: Laser Instrument, Surgical, Powered
Product Code: GEX
Panel: General & Plastic Surgery

3. Predicate Device

- Quantel Medical SUPRA SCAN™ Delivery System coupled to a SUPRA 532 (K100678)
- Topcon Medical Laser Systems PASCAL Streamline 577 (K111108)
- IRIDEX Corp, IQ 577 (K071687)

4. Device Description

SUPRA SCAN™ Delivery System is a scanning laser delivery system that enables the use of proprietary pattern scanning technology when coupling with laser platforms. This offers existing commercially available laser platform the ability to deliver a full spectrum of pattern scanning options.

The SUPRA SCAN™ Delivery System is intended for use by trained ophthalmologist for diagnosis and treatment of ocular pathology.

The Quantel Medical SUPRA SCAN™ Delivery System consists of the following system components:

1) Scanning Laser Delivery System adaptor with scanner controls that may be coupled to a slit lamp type Haag Streit or similar models, and connected to a currently cleared Quantel Medical 577nm retinal photocoagulator (SUPRA 5577.Y-K091581).

2) Scanner control module with LCD/Touch screen, power supply, electronics and electrical connections.

5. Indications for Use

The SUPRA SCAN™ Delivery System when connected to a compatible laser system is indicated for use in the treatment of ocular pathology of anterior and posterior segments including, retinal photocoagulation, pan retinal photocoagulation for vascular and structural abnormalities of the retina and choroids including:

- Proliferative and nonproliferative diabetic retinopathy;
- Choroidal neovascularization;
- Branch retinal vein occlusion;
- Treatment of choroidal neovascularization associated with wet age-related macular degeneration;
- Retinal tears and detachments
- Macular edema
- Retinopathy of prematurity
- Iridotomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma.

6. Substantial Equivalence

The SUPRA SCAN™ Delivery System shares the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate devices, the PASCAL Streamline 577

(K111108), the IQ 577 (K071687) and the Quantel Medical SUPRA SCAN™ Delivery System coupled to a SUPRA 532 (K100678). In addition a review of the predicate devices demonstrates that the SUPRA SCAN™ Delivery System is substantially equivalent to the predicate devices as they share equivalent specifications / characteristics and are used to perform the same indicated surgical procedures.

The only differences in the specifications/characteristics of the SUPRA SCAN™ Delivery System and its predicate PASCAL Streamline 577 (K111108) is that the SUPRA SCAN™ Delivery System has a maximum spot size of 500 microns instead of 400 microns for PASCAL Streamline 577 (K111108). This difference is not viewed as being clinically significant. The SUPRA SCAN™ Delivery System offers to treat at 400 microns with equivalent energy output performance. Additionally, the SUPRA SCAN™ Delivery System for use with a 532 nm laser uses a 500 micron spot size for similar indications for use.

The SUPRA SCAN™ Delivery System uses the same fundamental technology features as the PASCAL Streamline 577 (K111108). Therefore, it is concluded that SUPRA SCAN™ Delivery System is substantially equivalent to the identified predicate devices.

7. Performance Data

Laboratory testing was conducted to validate and verify that the SUPRA SCAN™ Delivery System met all design specifications and was substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2012

Quantel Medical
% O'Connell Regulatory Consultants, Incorporated
Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K120825
Trade/Device Name: SUPRA SCAN™ Delivery System
Regulation Number: 21 CFR 886.4390
Regulation Name: Opthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 09, 2012
Received: August 13, 2012

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

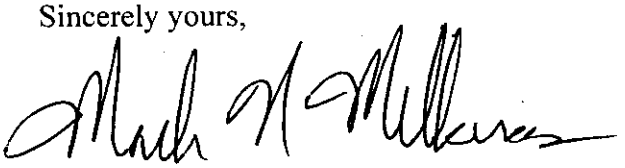
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: SUPRA SCAN™ Delivery System

Indications for Use:

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- Retinopathy of Prematurity
- Iridotomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma.

Prescription Use X___ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120825